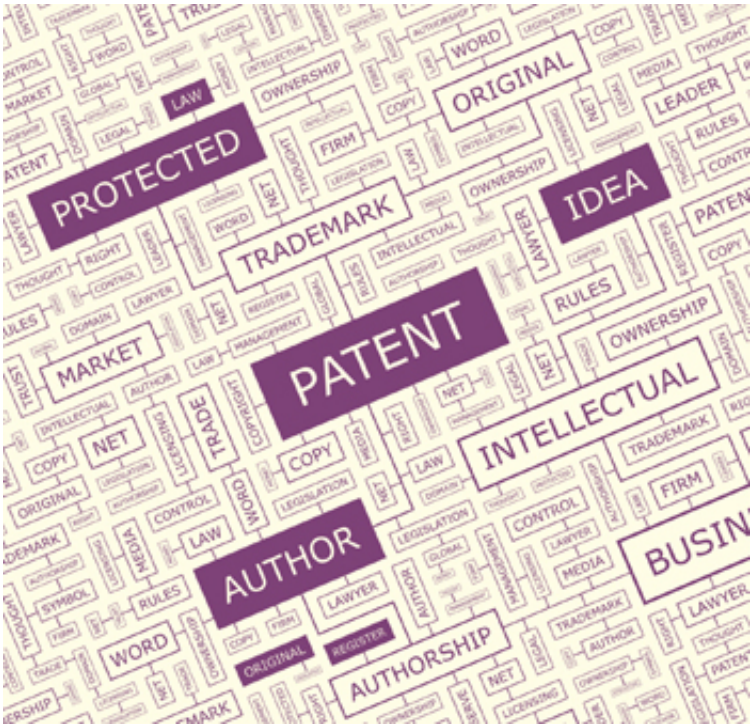
New patenting guidelines are needed for biotechnology

April 22 2014



Biotechnology scientists must be aware of the broad patent landscape and push for new patent and licensing guidelines, according to a new paper from Rice University's Baker Institute for Public Policy.

Published in the current issue of the journal *Regenerative Medicine*, the paper is based on the June 2013 U.S. Supreme Court ruling in the case

Association for Molecular Pathology (AMP) v. Myriad Genetics that naturally occurring genes are unpatentable. The court case and rulings garnered discussion in the public about patenting biological materials.

"The AMP v. Myriad Genetics case raises questions about the patent system," said Kirstin Matthews, the Baker Institute fellow in science and technology policy and an expert on ethical and policy issues related to biomedical research and development. She co-authored the paper with Maude Rowland Cuchiara, the Baker Institute scholar for science and technology policy. The paper has timely significance in light of President Barack Obama's recent announcements on reforming the nation's patent process, including an initiative announced in February to "crowdsource" the review of patents.

"There are not many opportunities to challenge patents once they have been granted, and the options that are available are costly and mostly limited to lawsuits," Matthews said. Judges typically do not have the scientific knowledge to understand some of the technical arguments that are made in their courts, she said. "It may be better, as President Obama has proposed, to revise patenting guidelines at the U.S. Patent and Trademark Office based on feedback from scientists, engineers, ethicists and policy scholars as opposed to leaving it up to the courts."

Until the Supreme Court's decision, Myriad Genetics was the only company in the U.S. that could legally conduct diagnostic testing for BRCA 1 and 2, genes that are linked to familial breast and ovarian cancer. The company was granted the patents in 1998 and 2000, respectively. Myriad chose not to license the patents and harshly pursued anyone who infringed on them.

"The patenting of the BRCA genes launched a raucous debate about the ability to patent life: How do we distinguish between what is simply discovered and what is truly 'made by man'?" the authors asked.

Biotechnological inventions have been patented for several decades, though the criteria for patent eligibility have been refined through numerous court decisions, according to the authors. One of the most influential was Diamond v. Chakrabarty, which determined that "anything under the sun made by man" could be patented, leading to the diverse biotechnology patent landscape seen today, the authors said. However, biotechnological patents must meet the same requirements as all other patents, and they cannot be laws of nature, physical phenomena or abstract ideas.

The authors said the ruling could affect the patentability of other biotechnologies, like stem cells, depending on how the ruling is interpreted. Stem cells, like genes, are also isolated from the body although they do require some manipulation after isolation. But it is likely that if stem cell patents include detailed procedures for the manipulations beyond isolation, they will be upheld. "However these types of patents could also be challenged for failing to meet other patenting requirements like non-obviousness – meaning that they were not really unique or original after all," the authors said.

Overall, it remains to be seen what impact the ruling in the AMP v. Myriad Genetics case will have on the biotech industry or if any patenting requirements will be changed in response to this or other court rulings, the authors said. So far, the patentability of biotechnological inventions appears to remain unaffected. "However, as more and more biotechnological inventions are patented, the line between what is and is not a 'product of nature' becomes blurred and will most likely continue to be decided in a courtroom," the authors said.

The authors suggest initial steps to address the current situation, including an outside review of patents before they are granted, reforming the rules of patent licensing to minimize restrictive practices and requiring detailed patent descriptions to prevent expensive and disruptive

lawsuits.

"Moving forward, scientists must be aware of the broad patent landscape and push for new patent and licensing guidelines," the authors said. "This could keep patents out of court, make the patenting process more seamless and help to spur innovation."

More information: "Gene Patents, Patenting Life and the Impact of Court Rulings on U.S. Stem Cell Patents and Research," *Regenerative Medicine*, 2014.

Provided by Rice University